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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/084,813	02/27/2002	Carl Saxinger	215875	6159
23460	7590	03/25/2004	EXAMINER	
LEYDIG VOIT & MAYER, LTD TWO PRUDENTIAL PLAZA, SUITE 4900 180 NORTH STETSON AVENUE CHICAGO, IL 60601-6780			PARKIN, JEFFREY S	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 03/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/084,813	SAXINGER, CARL	
	<b>Examiner</b>	<b>Art Unit</b>	
	Jeffrey S. Parkin, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-24,30,31,34-36,50 and 53-69 is/are pending in the application.
- 4a) Of the above claim(s) 1-20,22-24,30,31,34-36,50,53-59 and 61-69 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21 and 60 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>02272002</u> . | 6) <input type="checkbox"/> Other: _____  |

Serial No.: 10/084,813  
Applicant: Saxinger, C.

Docket No.: 215875  
Filing Date: 02/27/02

### Detailed Office Action

#### *Status of the Claims*

Applicant's election with traverse of Group IV (claims 21 and 60) in the communication filed 19 December, 2003, is acknowledged. The traversal is based upon the premise that the Office has failed to set forth a *prima facie* case for restriction. Applicant argues that significant overlap exists between the various groups claimed and would not constitute an undue burden, if examined concomitantly. This is not found persuasive for the reasons of record clearly set forth in the last Office action. Moreover, as applicant noted, two criteria currently exist for the determination of proper restriction requirements (see M.P.E.P. § 803) as follows: 1) The inventions must be independent (see M.P.E.P. § 802.01, § 806.04, § 808.01) or distinct as claimed (see M.P.E.P. § 806.05); and, 2) There must be a serious burden on the examiner if restriction is not required (see M.P.E.P. § 803.02, § 806.04(a)-(j), § 808.01(a), and § 808.02).

**Establishment of *prima facie* evidence for a serious burden requires the demonstration, by appropriate explanation, of either separate classification, separate status in the art, or a different field of search as defined in M.P.E.P. § 808.02.** The following reasons are adduced as a *prima facie* showing of burden: while some of Groups I-XXIV display a different classification and subclassification, nevertheless, the structural unrelatedness of these various peptides precludes their inclusion in a single group. Since each peptide has a different amino acid sequence, separate searches will be required for each peptide and methods employing said peptides.

Accordingly the **requirement is still deemed to be proper and is therefore made FINAL.** Claims 1-20, 22-24, 30, 31, 34-36, 50, 53-59 and 61-69 are withdrawn from further consideration by the examiner, pursuant to 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

**37 C.F.R. § 1.821-1.825**

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. § 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant is reminded that pursuant to 37 C.F.R. § 1.821(d), where the description or **claims** of a patent application discuss a sequence that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, **reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO.:" in the text of the description or claims,** even if the sequence is also embedded in the text of the description or claims of the patent application. Appropriate correction is required.

**37 C.F.R. § 1.98**

The information disclosure statement filed 27 February, 2002, has been placed in the application file and the information referred to therein has been considered.

**35 U.S.C. § 112, Second Paragraph**

Claims 21 and 60 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point

out and distinctly claim the subject matter which applicant regards as the invention. The claims contain the phrase "comprises less than about 100 amino acid residues" which is vague and indefinite since it clearly fails to set forth the metes and bounds of the patent protection desired. The precise size limitations encompassed by the claim language are not readily manifest. Appropriate correction is required.

### 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 21 is rejected under 35 U.S.C. § 102(b) as being clearly anticiapted by NG et al. (1997). This teaching discloses a polypeptide comprising the sequence LPP...NML (see p. 88, Table 4A).

### 35 U.S.C. § 103(a)

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

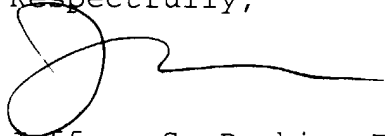
Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claim 60 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Ng et al. (1997). The authors disclose a polypeptide comprising the amino acid sequence LPP...NML. The authors further add that the peptides described in the claimed invention can be conjugated to a carrier or incorporated into a carrier system to increase plasma half-life (see pp. 20 and 21). Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to prepare a composition comprising the polypeptide of interest and a carrier since this would facilitate delivery of the polypeptide and retention of polypeptide activity.

#### **Correspondence**

Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 9:30 AM to 7:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisors, Laurie Scheiner or James Housel, can be reached at (571) 272-0910 or (571) 272-0902, respectively. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (571) 272-1600.

Respectfully,



Jeffrey S. Parkin, Ph.D.  
Patent Examiner  
Art Unit 1648

21 March, 2004